K002297

MAR 1 5 2001

XIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Morris Mizrahi, United Yoram Distributors, Inc., Brooklyn, NY. Phone: 718-875-1179.

I. Classification: Class II.

II. Common or usual name: TENS Device

III. Proprietary Name: Yoramed™, Series 200 (Model T-202)

IV. Registration No.: In process

V. Classification Name: Transcutaneous Electrical Nerve Stimulator, Class II, Code GZJ.

VI. Performance standards: No mandatory standards applicable.

VII. Description: The Yoramed™ Series 200 (Model T-202) is a non-invasive nerve stimulation therapy device, indicated for use in treatment of symptomatic relief of and management of long-term intractable pain and/or as an adjunctive treatment in the management of post-surgical or post-traumatic pain. It has an adjustable pulse amplitude, pulse rate, and pulse width, with an automatic modulation mode for the pulse width. It can be used in "normal" modes,"burst" mode or in "modulation" mode following the directions of the prescribing physician. Like the Graham-Field (and several other) devices it operates with a 9 V alkaline or nickel-cadmium rechargeable battery.

VIII. Labels and Labeling: Labels and labeling are provided including labels of competitive products.

IX. Substantial Equivalence: It is equivalent to several devices but especially to the SEIN SE-30 TENS device cleared through K-991937 and to the Graham-Field TENS Plus device cleared under K924876.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Mr. Morris Mizrahi
United Yoram Distributors, Inc.
602 Degraw Street
Brooklyn, New York 11217

Re: K002297/S1
Trade Name: Yoramed™ Model T-202 TENS
Regulatory Class: II
Product Code: GZJ
Dated: December 10, 2000
Received: December 15, 2000

Dear Mr. Mizrahi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Yoramed™, Series 200 (Model T-202)

Indications for Use:

Indicated for the symptomatic relief and management of chronic (long term) intractable pain and/or as an adjunct treatment in the management of post-surgical and post-traumatic acute pain.

f Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002297/S1

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)